

REMARKS/ARGUMENTS

In this response, claims 1, 25-27, 30, 33-36, 80, 89, and 100 are being amended, and no claims are being added or canceled. Thus, claims 1-48 and 80-100 remain pending in the application. Reconsideration and allowance of this application is respectfully requested in view of the remarks below.

Claim 1 is being amended to specify that the predicting disordered breathing “us[es] at least a first disordered breathing prediction criteria set”. The “estimating” subparagraph of claim 1 is then also being amended for consistency, to recite “estimating an accuracy of the first disordered breathing prediction criteria set”. Support for the amendments can be found throughout the as-filed application, such as from page 25, line 20 to page 27, line 16. No new matter has been added.

Dependent claims 25-27, 30, and 33 are being amended for clarity in view of the amendments to claim 1, to specify that the “one or more sets of prediction criteria associated with disordered breathing” (claim 25), the “one or more sets of disordered breathing threshold criteria” (claim 26), the “one or more sets of disordered breathing relationship criteria” (claim 27), and the “one or more sets of disordered breathing prediction criteria” (claims 30 and 33) include the “first disordered breathing prediction criteria set” of amended claim 1. Claim 33 is also being amended to avoid a potential ambiguity arising from the occurrence of the phrase “a particular set” in both original claim 33 and its dependent claims 35 and 36. Thus, claim 33 is being amended to change “adjusting a particular set …” to “adjusting at least one of the one or more … sets …”, and corresponding minor amendments are then also being made to claims 34-36 for optimal consistency. No new matter has been added.

Independent claims 80 and 100 are being amended in similar fashion to claim 1. In claim 80, the prediction engine is configured to predict disordered breathing “using at least a first disordered breathing prediction criteria set, the prediction engine also being configured to estimate an accuracy of the first disordered breathing prediction criteria set.” In claim 100, the predicting means predicts disordered breathing “using at least a first disordered breathing prediction criteria set”, and the estimating means estimates an

accuracy “of the first disordered breathing prediction criteria set”. No new matter has been added.

Dependent claim 89 is being amended for clarity in view of the amendments to base claim 80, to specify that the one or more sets of disordered breathing prediction criteria “includ[es] the first disordered breathing prediction criteria set”. No new matter has been added.

Claim Rejections – Obviousness-Type Double Patenting

The Office Action provisionally rejected claims 1-48 and 80-100 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-102 of copending application no. 10/643,016 (attorney docket no. GUID.088PA) in view of U.S. Patent 6,928,324 (Park et al.).

In response, Applicants respectfully request that this rejection be held in abeyance until allowable subject matter has been acknowledged by the Examiner in view of the provisional nature of the rejection and the policies set forth in MPEP § 804(I)(B)(1). Applicants also note that the ‘016 application has now issued as U.S. Patent 7,396,333 (Stahmann et al.), and it contains only 75 numbered claims rather than the 102 claims mentioned in the rejection.

Claim Rejections – § 112

The Office Action rejected claims 1-48 and 80-100 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. This rejection centered on the use of the phrase “estimating an accuracy of the disordered breathing prediction”, which appears in each of independent claims 1, 80, and 100.

In response, Applicants have amended the independent claims so that they each refer in some form to estimating an accuracy “of the first disordered breathing prediction criteria set”, rather than simply of the disordered breathing prediction. Applicants respectfully submit that these amendments render the rejections under 35 U.S.C. §112, first paragraph,

moot. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claim Rejections – § 103

The Office Action rejected claims 1-9, 14-18, 20, 22-27, 30-45, 47-48, 80-83, 85-86, 88-96, 98, and 100 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,126,611 (Bourgeois et al.), hereinafter “Bourgeois”, in view of U.S. Patent 6,366,813 (DiLorenzo). The Office Action states, among other things, that “[s]ince Bourgeois et al. detects an indication of the onset of sleep apnea, Bourgeois et al. predicts disordered breathing.” This rejection cannot be sustained.

The Office Action provides no response to, and not even an acknowledgment of, Applicants’ argument in their October 4, 2007 Response that since *onset* refers to “the beginning of something”, and since *predicting* refers to “say[ing] or estimat[ing] that a specified thing will happen in the future, Bourgeois’ disclosure of detecting the *onset* of sleep apnea in no way teaches “predicting disordered breathing” as set forth in claim 1, for example. Bourgeois’ disclosure of detecting an episode of sleep apnea once it has already begun does not constitute predicting the occurrence of sleep apnea. By analogy, if someone were to detect the *onset* of a rainstorm by feeling raindrops, we would not say that person has predicted the rainstorm.

Applicants maintain this argument and traverse the Examiner’s contention that Bourgeois teaches “predicting disordered breathing” (claim 1), or a prediction engine “configured to predict disordered breathing” (claim 80), or “means for predicting disordered breathing” (claim 100). DiLorenzo does not remedy these shortcomings of Bourgeois, and therefore the rejection of claims 1, 80, 100, and their respective dependent claims 2-9, 14-18, 20, 22-27, 30-45, 47-48, 81-83, 85-86, 88-96, and 98 under § 103 based on the combination of Bourgeois and DiLorenzo cannot be sustained and should be withdrawn.

The Office Action also asserts that “DiLorenzo teaches that it is known to estimate, or model, of fluctuation may be based upon a combination of preset, learned, and real-time sensed parameters as set forth in column 42, lines 50-60, for the purpose of prediction of

future symptomatology, cognitive and neuromotor functionality, and treatment magnitude requirements”, and that it would have been obvious “to have modified the predictive criteria as taught by Bourgeois et al. with the estimation of the accuracy of predictive criteria as taught by DiLorenzo, in order to provide the predictable results of determine relevant data, prevent outliers and create accurate predictions.”

Applicants strongly disagree with this conclusory argument. It would not have been obvious to modify predictive criteria taught by Bourgeois at least because Bourgeois has nothing to say about the prediction of disordered breathing, as explained above. Furthermore, the Office Action fails to explain how DiLorenzo’s prediction of future fluctuations based on prior characterization of circadian fluctuation in symptomatology “that is, tremor magnitude for deep brain stimulation or level of depression for stimulation of other sites including locus ceruleus” (col. 42, lines 37-41), in an intracranial stimulation device (col. 1, lines 16-20), would be expected to have any applicability whatsoever to the pacemaker system discussed in Bourgeois, much less how it would be expected to “determine relevant data”, “prevent outliers”, or “create accurate predictions” in Bourgeois’ system. No convincing rationale has been given for the proposed combination, and the rejection of claims 1-9, 14-18, 20, 22-27, 30-45, 47-48, 80-83, 85-86, 88-96, 98, and 100 should be withdrawn for this additional reason.

The Office Action went on to reject claims 19-21, 43-44, 46, 84, and 99 under 35 U.S.C. §103(a) as being unpatentable over Bourgeois in view of DiLorenzo (referred to in the Office Action as “the modified Bourgeois et al.”). The Office Action rejected claims 10-13 and 87 under 35 U.S.C. §103(a) as being unpatentable over Bourgeois in view of DiLorenzo, and further in view of U.S. Patent 6,398,728 (Bardy). The Office Action rejected claim 97 under 35 U.S.C. §103(a) as being unpatentable over Bourgeois in view of DiLorenzo, and further in view of U.S. Patent 5,335,657 (Terry, Jr. et al.).

In response, Applicants note that none of these rejections cites any further teaching that would remedy the shortcomings of Bourgeois and DiLorenzo, as discussed above. Claims 10-13, 19-21, 43-44, 46, 84, 87, 97, and 99 are therefore submitted to be allowable

at least for the reasons given above regarding the allowability of base claims 1 and 80. The rejection of claims 10-13, 19-21, 43-44, 46, 84, 87, 97, and 99 should be withdrawn.

To the extent Applicants have not responded to any characterization by the Examiner of the asserted art or of Applicants' claimed subject matter, or to any application by the Examiner of the asserted art to any claimed subject matter, Applicants wish to make clear for the record that any such lack of response should not be interpreted as an acquiescence to such characterizations or applications. A detailed discussion of each of the Examiner's characterizations, or any other assertions or statements beyond that provided above is unnecessary. Applicants reserve the right to address in detail any such assertions or statements in future prosecution.

CONCLUSION

For the foregoing reasons, claims 1-48 and 80-100 are all submitted to be in condition for allowance, the early indication of which is earnestly solicited. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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